

REMARKS

The present application has been considered in view of the Non-Final Office Action that was mailed on April 18, 2011. Claims 18, 29-34, and 36-39 are currently pending. By the present Amendment, Applicants have amended claims 18 and 29 and added new claims 36-41. Applicants respectfully submit that the amendments to the claims effected herein do not introduce any new matter, are fully supported by the specification, and do not necessitate any further search of the prior art by the Examiner. In view of the following remarks and arguments, Applicants respectfully submit that each of pending claims 18, 29-34, and 36-41 is allowable over the references of record, and accordingly, respectfully request reconsideration and allowance of these claims.

Allowable Subject Matter

As an initial matter, Applicants wish to thank the Examiner for indicating that the subject matter of claim 18 would be allowable if combined with the additional limitations set forth in claim 29, more specifically, the requirement of recesses in the elongated shaft adjacent its distal end, the inwardly depending tissue contacting portions of the jaw members being configured and dimensioned for receipt by the recesses. (Office Action, page 14).

By the present amendment, Applicants have added new claim 41 which includes the subject matter of claim 18 and the limitations of claim 29 described above. Accordingly Applicants respectfully submit that new claim 41 is in condition for allowance over the prior art of record.

Rejections under 35 U.S.C. §112

In the Office Action, claims 18 and 29-34 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Specifically the Office Action indicated that Applicants failed to disclose “at least one of the jaw members includes an attachment member formed of conductive material for facilitating transmission of energy to tissue or dimensioned for receipt by the recesses in the shaft.” (Office Action, page 4).

For clarity, applicants have amended claims 18 and 29 to replace “attachment member” with “tissue contacting surface” as can be found in Applicants’ specification as originally filed at least at page 8, lines 1-7 and page 10, lines 1-9.

Specifically on page 10, lines 1-9, of Applicants’ Specification it is disclosed that:

“In one embodiment, the contacting surface 44 of each jaw member functions as the RF electrode and is electrically connected through lead lines (not shown) to the RF power source.” and “It is also envisioned that the jaw members 40 may be conductive with the extreme tissue contacting portion 42 left uninsulated to transmit thermal energy.”

In addition on page 8, lines 2-4, of Applicants’ Specification it is also disclosed that:

“In the closed position of jaw members 40, depicted in FIG. 3 (reproduced below), tissue contacting portions 42 are received within corresponding recesses 46 of elongated shaft 18 to define the reduced profile shown”

In view of the foregoing, Applicants respectfully submit that the recitation of “wherein the tissue contacting surface is formed from a conductive material” in claim 18 and “the tissue

contacting surfaces being further configured and dimensioned for receipt by the disposed in spaced relation to the distal end of the elongated shaft” in claim 29 are sufficiently described in the Specification. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 18 and 29-34 under U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §103

Claim 18 was rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,507,744 to Tay, *et al.* (hereinafter “Tay”) in view of U.S. Patent No. 6,165,183 to Kuehn, *et al.* (hereinafter “Kuehn”).

Applicants respectfully submit that the combination of Tay and Kuehn fails to render the subject matter of amended independent claim 18 obvious, as presented herein.

Amended claim 18 recites, *inter alia*, an apparatus for substantially closing a vascular opening in a vessel while permitting post operative blood flow through the vessel, which comprises:

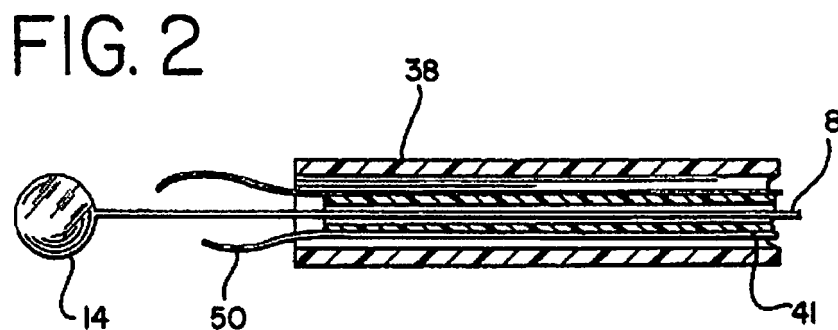
“a housing **including a sleeve** and having proximal and distal ends, and defining a longitudinal axis;

an elongated shaft at least partially disposed in the housing; ...

jaw members connected to the sleeve and positioned adjacent the tissue engaging members and being movable independently thereof, **the jaw members adapted to longitudinally move from a first longitudinal position corresponding to a closed position to a second longitudinal position corresponding to an open position upon longitudinal movement of the sleeve relative to the elongated shaft**, the jaw members adapted for seizure of the vascular tissue when in the open position, drawing together the vascular tissue during closing

of the jaw members, and rendering the vascular tissue in adjacent relation when in the closed position of the jaw members, wherein at least one of the jaw members includes a tissue contacting surface". (**Emphasis** added).

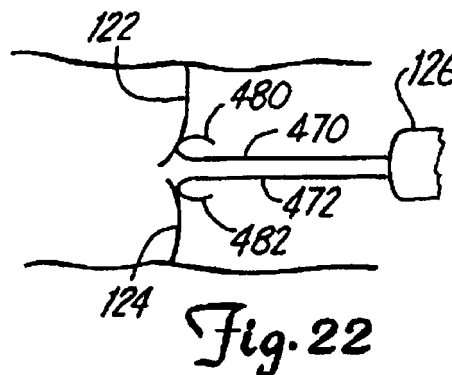
Tay relates an apparatus for closing and sealing vascular punctures. (Column 1, lines 12-13). In one embodiment of the disclosure, Tay describes a cautery device 7 including forceps 50 and having a tubular retaining housing 38 and an inner tubular housing 41 inside tubular retaining housing 38. (Column 5, lines 61-65; FIG. 2 reproduced below). The inner tubular housing 41, along with the tubular retaining housing 38, are used to guide the forceps 50 to the puncture site. (Column 6, lines 26-29; FIG. 2 reproduced below). In their first position, forceps 50 reside substantially inside tubular retaining housing 38. Upon actuation, the forceps 50 extend beyond the tubular retaining housing 38 and expand slightly due to the lack of radial compression provided by the retaining housing 38. (Column 10, lines 65-67; FIG. 2 reproduced below).



Applicants respectfully submit however that Tay fails to disclose at least that forceps 50 are "connected to the sleeve" or that forceps 50 are "adapted to longitudinally move from a first longitudinal position corresponding to a closed position to a second longitudinal position corresponding to an open position upon longitudinal movement of the sleeve relative to the

elongated shaft,” as recited by claim 18. Rather, as discussed above, the forceps 50 of Tay reside substantially inside tubular retaining housing 38 and upon actuation, the forceps 50 extend beyond the tubular retaining housing 38 and expand slightly due to the lack of radial compression provided by the retaining housing 38. There is no disclosure in Tay of the forceps 50 being actuated by longitudinal movement of a sleeve or that the forceps 50 of Tay are even connected a sleeve.

Kuehn relates to “the repair of mitral and tricuspid valves exhibiting valve regurgitation,” and more particularly, “to apparatus and methods suitable for a less invasive repair of a mitral or tricuspid heart valve.” (Column 1, lines 5-8). In one embodiment of the disclosure, Kuehn describes a cardiac catheter 126 through which hooks 470, 472 are deployed for grasping leaflets 122, 124 of the mitral valve. (Column 10, lines 4-14; FIG. 22 reproduced below).



Kuehn was relied upon by the Examiner to disclose the “tissue engaging members each having a distal segment arranged in a general hook or J-shaped configuration,” as recited by amended claim 18. (Office Action, page 5). Applicants respectfully submit, however, that Kuehn fails to cure the deficiencies of Tay discussed above with regard to amended claim 18.

For example, Kuehn fails to disclose at least “jaw members connected to the sleeve and positioned adjacent the tissue engaging members and being movable independently thereof, the jaw members adapted to longitudinally move from a first longitudinal position corresponding to a closed position to a second longitudinal position corresponding to an open position upon longitudinal movement of the sleeve relative to the elongated shaft,” as recited by amended claim 18. Rather in one embodiment of Kuehn, as shown in FIG. 18A reproduced below, the jaws 414 and 416 are actuated by a rod 422 where the extension of rod 422 alters the relative position of jaws 414 and 416. (Column 9, lines 5-19). Alternatively, as seen in FIG. 18B reproduced below, jaw 411 rotates around pivot 413 and rotation of rod 415 causes ball 417 to change position relative to rod 415. (Column 9, lines 20-31).

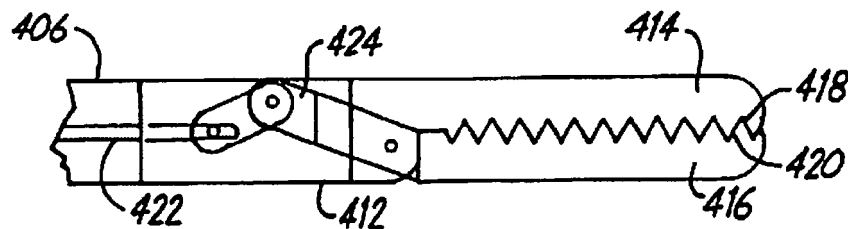


Fig. 18A

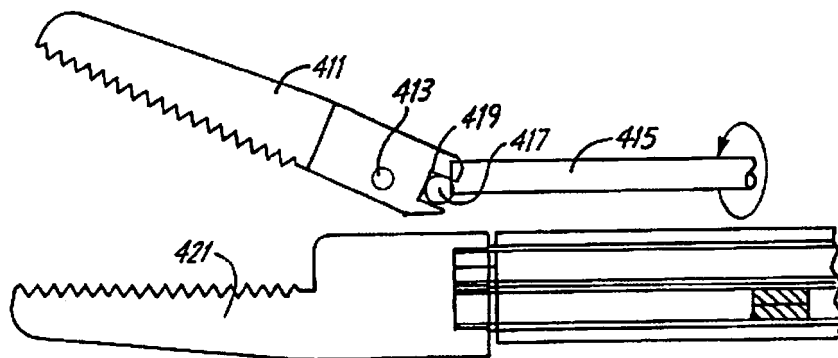


Fig. 18B

Nowhere in Kuehn is it disclosed that the jaw members are connected to a sleeve or that the jaw members are adapted to longitudinally move from a first longitudinal position corresponding to a closed position to a second longitudinal position corresponding to an open position upon longitudinal movement of the sleeve relative to the elongated shaft, as recited by amended claim 18.

Accordingly, and for at least this reason, *inter alia*, Applicants respectfully submit that the combination of Tay and Kuehn, taken alone or in any proper combination, fails render the subject matter of independent claim 18 obvious. As such, Applicants respectfully submit that independent claim 18 is allowable over Tay in view of Kuehn under 35 U.S.C. §103(a).

Claims 29, 30 and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,762,613 to Sutton, *et al.* (hereinafter "Sutton") in view of U.S. Patent No. 5,290,299 to Fain, *et al.* (hereinafter "Fain").

Applicants respectfully submit that the combination of Sutton and Fain fails to render the subject matter of claims 29, 30 and 32 obvious, as presented herein.

Amended independent claim 29 recites, *inter alia*, an apparatus for substantially closing a vascular opening in a vessel while permitting post operative blood flow through said vessel, which comprises:

"an elongated shaft at least partially positioned within the housing ...**the elongated shaft further including recesses disposed in spaced relation to the distal end;**" and "jaw members connected to the housing ... **the jaw members including tissue contacting surfaces the free ends of which depend radially inwardly therefrom towards the longitudinal axis, ... the tissue contacting surfaces being further configured and dimensioned for receipt by the**

recesses disposed in spaced relation to the distal end of the elongated shaft.” (Emphasis added).

Sutton relates to “the field of medical diagnosis and treatment,” and more specifically, “to a forceps device having integrated optical fiber and remotely controllable biopsy forceps functions, and to the use thereof in medical diagnosis.” (Column 1, lines 4-8). In one embodiment of the disclosure, Sutton describes forceps 10 that include a handle portion 12, a middle portion 14, a distal end 16 that includes opposed cutting jaws 80, 81. (Column 3, lines 45-50; FIGS. 1, 2 below).

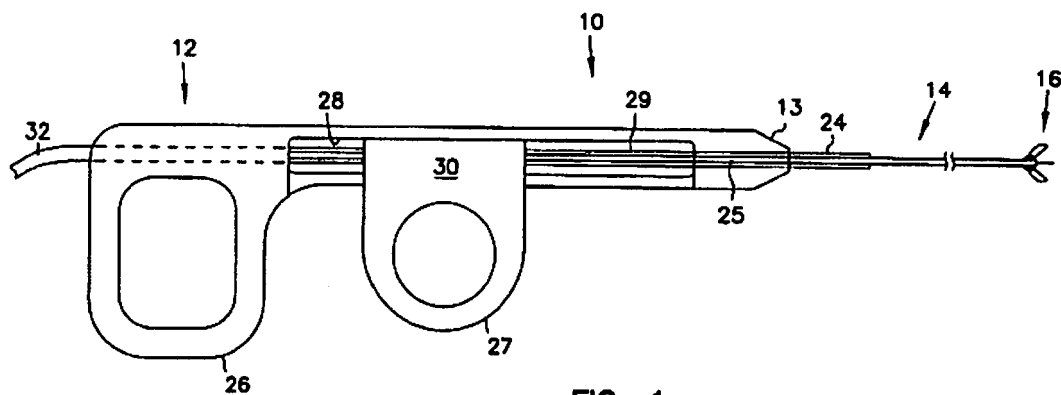


FIG. 1

The forceps 10 further include a main body with an inner tubular member 20, and an outer tubular member 22 that passes through a plastic sleeve 24, which serves as a reinforcing, strain relief member. (Column 3, lines 51-55; *see* col. 4, lines 1-3; FIG. 1 above; FIG. 2 below).

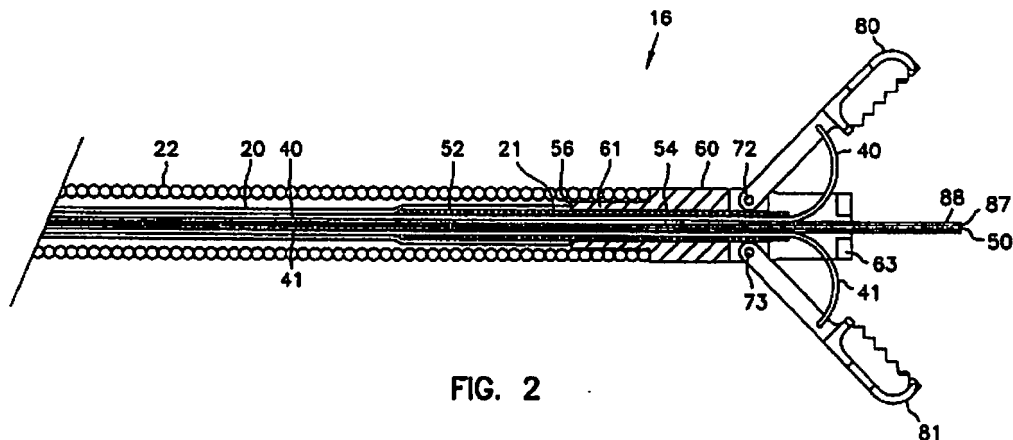


FIG. 2

As seen above in FIG. 2, a pair of control wires 40, 41, and an optical fiber 50 are positioned within the inner tube 20. (Column 3, lines 64-65).

Continuing, Sutton discloses that the distal end 16 of the forceps 10 includes a yoke 60, which serves as a mounting member for the cutting jaws 80, 81. (See col. 4, lines 34-36; FIG. 2 above). The yoke 60 includes a proximal section 61, a center section 62, and a distal section 63 with a vertical slot 70 that is dimensioned to allow for movement of the lever arms 85 supporting the jaws 80, 81. (Column 4, lines 38-41, 62-64; FIGS. 5A, 5C below).

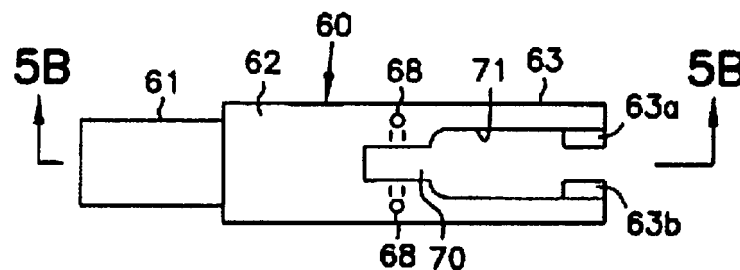
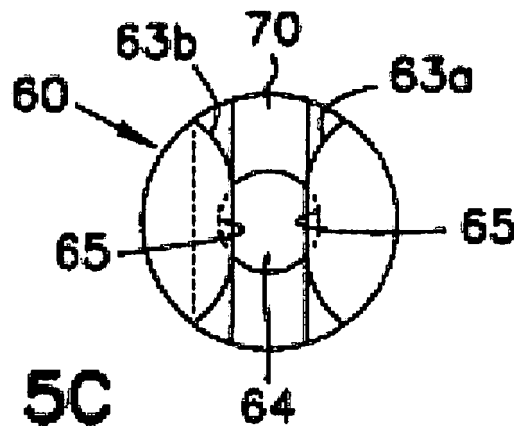


FIG. 5A

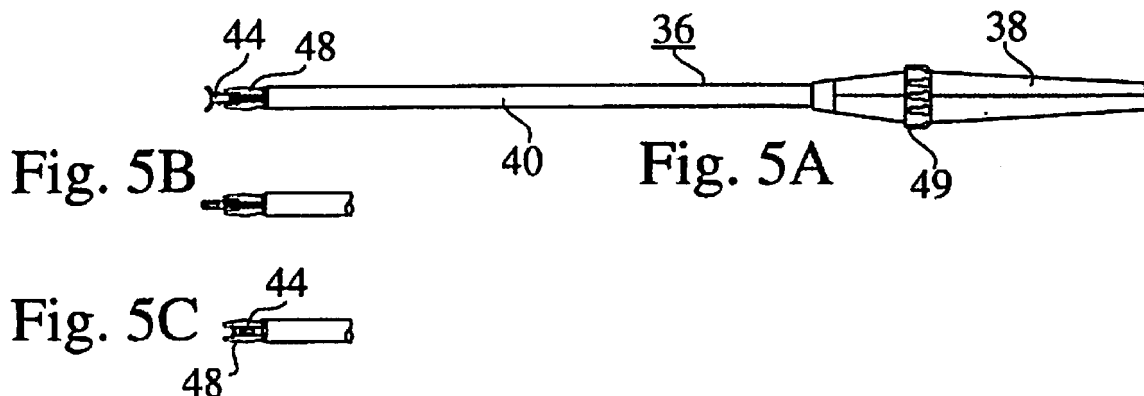


In the Office Action, the vertical slot 70 and control wires 40 and 41 of Sutton were respectively characterized as the “recesses formed adjacent the distal end,” and the “attachment members,” recited in the claims. (Office Action, pages 6). However Applicants respectfully submit that Sutton fails to teach, disclose or suggest at least “the elongated shaft further including recesses disposed in spaced relation to the distal end,” “the jaw members including tissue contacting surfaces the free ends of which depend radially inwardly therefrom towards the longitudinal axis,” and “the tissue contacting surfaces being further configured and dimensioned for receipt by the recesses disposed in spaced relation to the distal end of the elongated shaft”, as recited by amended claim 29.

Rather, as discussed above and seen in FIG. 5C above, the vertical slot 70 of Sutton extends from the distal end and is not disposed in spaced relation to the distal end as recited. In addition, as seen in FIG. 2 above, the control wires 40 and 41 extend through inner tube 20 and are attached to jaw members 80 and 81 rather than including free ends which depend radially inwardly from the jaw members, as recited. Finally control wires 40 and 41 are not configured

and dimensioned for receipt by recesses disposed in spaced relation to the distal end. Instead, as discussed above, the vertical slot 70 is not spaced from the distal end but rather extends from the distal end. Applicants respectfully submit that Fain fails to cure the deficiencies of Sutton with regard to amended claim 29.

Fain relates to “a method and apparatus for attaching implanted materials or devices to tissue inside the body.” (Column 1 lines 9-11). In one embodiment of the disclosure, Fain describes a fastening tool 36 for use with fasteners 20, 22 that includes a handle 38, a shaft 40 that extends distally from the handle 38, a lever 42 that is carried by the handle 38 for actuating a first pair of jaws 44, and a trigger 46 that is also carried by the handle 38 for actuating a second pair of jaws 48. (Column 4, lines 45-47; column 4, lines 67 – col. 5, line 4; FIGS. 1-4; FIGS. 5A-5C below).



While it was acknowledged that Sutton fails to disclose “tissue engaging members,” Fain was relied upon for disclosure of this concept with reference to the jaws 44 seen above in FIGS. 5A and 5C. (Office Action, pages 6-7).

Even if it is assumed, *arguendo* that the characterization of Fain proffered in the Office Action is accurate, and that Sutton and Fain are properly combinable under the MPEP, including

the “tissue engaging members” purportedly disclosed in Fain would fail to cure the
aforedescribed deficiencies in Sutton.

Accordingly, and for at least this reason, *inter alia*, Applicants respectfully submit that
the combination of Sutton and Fain fails to suggest the subject matter of independent claim 29 as
a whole, and therefore, that the combination of Sutton and Fain fails to render the subject matter
of independent claim 29 obvious. As such, Applicants respectfully submit that independent
claim 29 is allowable over Sutton in view of Fain under 35 U.S.C. §103(a). Since claims 30 and
32 depend directly and indirectly from independent claim 29, respectively, and include each
element recited therein, for at least the reasons that independent claim 29 is allowable over
Sutton in view of Fain under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that
claims 30 and 32 are also allowable over Sutton in view of Fain under 35 U.S.C. §103(a).

Claims 31, 33, and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over
Sutton and Fain, as applied to claim 29 above, in further view of Kuehn. Applicants respectfully
submit, however, that the combination of Sutton, Fain, and Kuehn fails to render the subject
matter of claims 31, 33, and 34 obvious.

In the Office Action, it was acknowledged that the combination of Sutton and Fain fails
to disclose “two tissue engaging members comprise [*sic*] two hooks or a J-shaped configuration
disposed in general diametrical opposed relation in the advanced position, wherein the engaging
members are composed of a shape memory alloy,” as substantially recited in claims 31, 33, and
34, but Kuehn was relied upon for disclosure of this concept in combination with elements
allegedly known in the art, i.e., shape memory materials. (Office Action, pages 7-8).

Even if it is assumed, *arguendo*, that the characterization of Kuehn proffered in the Final
Office Action is accurate, and that Sutton, Fain, and Kuehn are properly combinable under the

MPEP, incorporating the “tissue engaging members” purportedly disclosed in Kuehn would fail to remedy the aforescribed deficiencies in the combination of Sutton and Fain.

Accordingly, and for at least this reason, *inter alia*, Applicants respectfully submit that the combination of Sutton, Fain, and Kuehn fails to suggest the subject matter of independent claim 29 as a whole, and therefore, that the combination of Sutton, Fain, and Kuehn fails to render the subject matter of independent claim 29 obvious. As such, Applicants respectfully submit that independent claim 29 is allowable over Sutton in view of Fain and Kuehn under 35 U.S.C. §103(a). Since claims 31, 33, and 34 depend indirectly from independent claim 29, and include each element recited therein, for at least the reasons that independent claim 29 is allowable over Sutton in view of Fain and Kuehn under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claims 31, 33, and 34 are also allowable over Sutton in view of Fain and Kuehn under 35 U.S.C. §103(a).

Double Patenting

Claims 18 and 29-34 were also rejected on the ground of non-statutory obviousness-type double patenting over claims 1-9 of U.S. Patent No. 6,248,124 (hereinafter “the ‘124 patent”), claims 1-25 of U.S. Patent No. 6,676,685 (hereinafter “the ‘685 patent”), and claims 1-6 of U.S. Patent No. 7,252,666 (hereinafter “the ‘666 patent”).

Applicants respectfully request reconsideration of the aforementioned double patenting rejections in view of the amendments to the claims effected herein. Upon such review, should it be determined that the aforementioned double patenting rejections are appropriate, upon the indication that claims 18 and 29-34 are otherwise allowable, Applicants will execute a terminal

disclaimer with respect to claims 1-9 of the '124 patent, claims 1-25 of the '685 patent, and claims 1-6 of the '666 patent in the interests of advancing prosecution.

New Claims

As mentioned above, Applicants have added new claims 36-41 for consideration herein. Applicants respectfully submit that new claims 36-41 recite a unique combination of features that is neither taught, nor suggested, by the references of record. Moreover, since new claims 36-38 and 39-40 depend either directly or indirectly from one of amended independent claims 18 and 29, which Applicants respectfully submit are allowable in view of the discussion above, and include each element recited therein, for at least the reasons that amended independent claims 18 and 29 are allowable, *inter alia*, Applicants respectfully submit that new Claims 36-38 are also allowable. New claim 41 recites the subject matter which was indicated by the Examiner to be allowable on page 14 of the Office Action. Accordingly, Applicants respectfully submit that new claim 39 is also allowable.

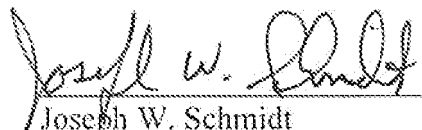
Conclusion

In view of the foregoing remarks and arguments, Applicants respectfully submit that claims 18 and 29-34 and 36-41 are allowable over the references of record, and accordingly, respectfully request reconsideration and allowance of these claims.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, or resolve any outstanding matter, the Examiner is sincerely invited to contact Applicants' undersigned representative at the number indicated below.

Please charge any deficiency, as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required, and charge Deposit Account No. 21-0550 accordingly.

Respectfully submitted,


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